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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,599	04/02/2007	Benjamin Guy Davis	7765P001	6198

8791 7590 04/26/2010
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EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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04/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,599	Applicant(s) DAVIS ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/09, 4/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V in the reply filed on January 14, 2010 is acknowledged.

Claims 1-26 and 28-32 are pending. Claims 1-22, 24-26, 28 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 14, 2010.

Claims 23 and new claims 30-32 have been examined on the merits.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by ENGMAN (L. Engman et al. Tetrahedron (1994) 50(9), pages 2929-2938).

Engman teaches reacting glutathione, a thiol containing organic compound, with glutathione-Se-Ph (GSSePh), a peptide comprising at least one selenenysulfide group, to form GSSG and releasing PhSeH (e.g. scheme 3, page 2931). GSSePh is formed via reaction of GSH and PhSeBr (e.g. scheme 2 page 2931).

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Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by HSIEH (H.S. Hsieh et al. Biochemistry (1975) 14(8), pages 1632-1636).

Hsieh teaches the reaction of GSSeH with GSH to form H₂Se and GSSG (e.g. scheme 3, page 1635).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

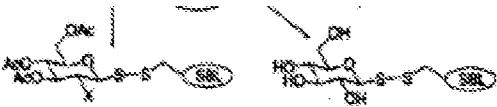
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIS (B.G. Davis et al. Tetrahedron: Asymmetry (2000) 11, pages 245-262; IDS 4/5/07), ENGMAN (L. Engman et al. Tetrahedron (1994) 50(9), pages 2929-2938), above, HSEIH (H.S. Hsieh et al. Biochemistry (1975) 14(8), pages 1632-1636), above, and WONG (US Patent 5,759,823).

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The instant claims are drawn generally to a method of modifying a peptide/protein/amino acid having a selenenylsulfide group via reacting with an organic compound comprising a thiol, with the specific compound being reacting GlcSH with SBL-S156-Se-Ph.

Davis teaches SBL S156 is useful for glycosylation as "S156 is a surface-exposed residue that permits the introduction of externally disposed glycans resembling those found naturally in glycoproteins." (page 246). SBL is a serine protease (e.g. Abstract). Davis teaches a variety of

sugars attached to SBL, for example:  , with the 2nd structure being SBL-Glc (e.g. scheme 2, page 248).

Engman and Hsieh teach the reaction of a selenenylsulfide with a thiol containing compound (above). Wong teaches "Thiosugar acceptor saccharides, such as thioglucose are available from commercial sources (Sigma Chemical Co., St. Louis, Mo.)." (column 19, lines 4-6).

The difference between the instant claims and the teachings of Davis, is that while Davis teaches the product SBL-Glc, it does not teach the specific position of the modification (e.g. C156), nor does it teach the use of the thioglucose (Glc-SH) or the selenenylphenyl modified compound. It would have been obvious at the time of the invention to have used SBL(C156) as the base compound, as it is a protein that "permits the introduction of externally-disposed glycans resembling those found naturally in glycoproteins." Furthermore, one would have used the selenenylphenyl as the product released, PhSeH, can be used as a spectroscopic means to follow the reaction to completion, as the Soret band of the benzene-selenolate is red shifted form that of the peptide/protein bound phenylselenenyl compound. Furthermore, the starting material-

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thiolglucose (Glc-SH), and other thiol sugars are commercially available, as opposed to the thiol sugar of Davis, which requires formation using an N-Ac halogenated sugar with $\text{NaSSO}_2\text{CH}_3$ in ethanol at 90°C for one hour or in DMF at RT for 2 hours. Thus, the artisan would recognize the advantage of using a starting material that is commercially available that reacts readily to form the final product. Furthermore, one would recognize using commercially available starting materials would employ a different synthetic route than that of Davis, and in looking to the art, would understand that the cysteine would require a selenenylsulfide group for the reaction to occur.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654